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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,757	02/08/2001	Yechezkel Barenholz	BARENHOLZ=1	6619

7590 04/18/2002
Browdy and Neimark
624 Ninth Street, N. W.
Washington, DC 20001

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,757

Applicant(s)

BARENHOLZ ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-13, 17 and 18 in Paper No. 10 is acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1-11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuidam et al (Biochim. Biophys. Acta (1998) 1368:115-128) in view of Gee et al (U.S. Patent 5,830,912).

Zuidam teaches a method for determining binding of a nucleic acid biomolecular species at a lipid surface having a local environment at a given pH or surface potential

wherein the binding is effective to alter said pH or potential (abstract) comprising the steps:

(a) stably incorporating at said surface a probe, here 4-heptadecyl-7-hydroxycoumarin, which comprises a potential and pH sensitive fluorophore attached to a lipid (page 117, subheading "liposome preparation"),

(b) observing a change in a fluorescent property of said fluorophore upon binding of said nucleic acid species to said lipid bilayer with cationic head groups (see page 117, figure 1 for observational data and page 117, column 1 for cationic nature of liposomes)

Zuidam further teaches a biomolecule with groups which are charged at pH between 4.5 and 7.5 and a surface which is also charged in this pH range (see page 117, column 1, with Hepes at pH 7.4).

The hydroxycoumarin label of Zuidam will be necessarily buried within the lipid bilayer due to the presence of the alkyl chain.

Zuidam does not teach the probe having two alkyl chains of 14 carbons in length, nor does Zuidam teach that the lipid is a phospholipid.

Gee teaches a composition which is a fluorescent probe, comprising a coumarin fluorophore linked to a phospholipid with two alkyl chains of greater than 14 carbons in length (see column 11, compound 68) and suggests the use of this compound in interactions with lipoproteins (column 23, lines 23-28).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the probe of Gee in the method of Zuidam since


Gee states "Dye compounds that possess a lipophilic substituent at R3 or R4 or that are conjugated to lipophilic molecules such as phospholipids will noncovalently incorporate into lipid assemblies, e.g. for use as probes for membrane structure or for incorporation in liposomes, lipoproteins, films plastics, lipophilic microspheres or similar materials (column 23, lines 23-28)." Thus, an ordinary practitioner would have been motivated to use compound 68, with it's lipophilic substituents, in the method of Zuidam in the place of 4-heptadecyl-7-hydroxycoumarin as a probe for membrane structure and incorporation into liposomes since Gee teaches that these are useful in those methods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER
Jeffrey Fredman
Primary Examiner
Art Unit 1637

April 9, 2002